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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,441	03/08/2004	Michael Radomsky	DEPYP003D1C1	1814

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BEYER WEAVER LLP
P.O. BOX 70250
OAKLAND, CA 94612-0250

EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,441	RADOMSKY, MICHAEL	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-20* is/are rejected.

7)☒ Claim(s) *21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/16/07.

The amendment filed 01/16/07 affects the application, 10/796,441 as follows:

1. The responsive to applicants' arguments is contained herein below.

Claims 17-22 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyoshi et al. (JP 04282322).

In claim 17, applicant claims "A method of treating diseased, injured or abnormal bone at a site of desired bone growth comprising the step of applying to said site a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist at said site for a period of time sufficient to enhance said bone growth rate and magnitude." Miyoshi et al. disclose applicant's method of treating diseased bone (bone diseases) with a composition comprising an effective amount of a mixture of hyaluronic acid (sodium hyaluronate), a growth factor (transforming growth factor) and excipient (saline) (see abstract). Furthermore, although Miyoshi et al. is silent about the properties or characteristics of the

composition which pertains to its biodegradability, effect of enhancing bone growth rate and magnitude and viscosity, Miyoshi et al.'s composition is the same as applicant's composition (comprising growth factor, hyaluronic acid and saline as an excipient), and consequently it should inherently possess the same properties. Claims 19 and 20, which are drawn to compositions of claim 17 wherein the hyaluronic acid is uncrosslinked and hyaluronic acid of specific range of % by weight in solution, are also encompassed by this rejection, since Miyoshi et al. hyaluronic acid is uncrosslinked and contains the same % by weight of hyaluronic acid (i.e., 0.5%) (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyoshi et al. (JP 04282322).

In claim 17, applicant claims "A method of treating diseased, injured or abnormal bone at a site of desired bone growth comprising the step of applying to said site a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist at

said site for a period of time sufficient to enhance said bone growth rate and magnitude." Claim 18 is drawn to a composition according to claim 17 wherein said viscosity is about 75,000 cP.

Miyoshi et al. disclose a method of treating diseased bone (bone diseases) with a composition comprising an effective amount of a mixture of hyaluronic acid (sodium hyaluronate), a growth factor (transforming growth factor) and excipient (saline) (see abstract). Furthermore, although Miyoshi et al. is silent about the properties or characteristics of the composition which pertains to its biodegradability, effect of enhancing bone growth rate and magnitude and viscosity, Miyoshi et al.'s composition is the same as applicant's composition (comprising growth factor, hyaluronic acid and saline as an excipient), and consequently it should inherently possess the same properties.

The difference between applicant's claimed method and the method taught by Miyoshi et al. is the viscosity of the composition. However, the use of compositions containing the same components but of different viscosities depends on factors such as the severity of the bone disease and the individual that is being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method of Miyoshi et al. to treat bone disease with a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients and to alter the viscosity of said composition depending on factors such as the severity of the bone disease and the individual that is being treated.

One having ordinary skill in the art would have been motivated to use the method of Miyoshi et al. to treat bone disease with a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients and to alter the viscosity of said

composition depending on factors such as the severity of the bone disease and the individual that is being treated.

Allowable Subject Matter

Claims 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Though the method of the present invention are similar to the method of the prior art, the method of claims 21-22 are different, not suggested and are unobvious over the prior art. Moreover, the prior art document does not teach or suggest treating diseased, injured or abnormal bone with a combination of hyaluronic acid, a bFGFgrowth factor and excepient. Moreover, applicant's composition which comprises a mixture of hyaluronic acid, a bFGF growth factor and excipients produces a synergistic effect of treating bone growth.

Response to Amendment

Applicant's arguments with respect to claim 17-20 have been considered but are not found convincing.

The applicant argues that throughout the specification of the present application, it is seen that the hyaluronic acid is used as a gel. This gel-like consistency is important since the composition is applied at the site of the bone fracture or defect and must persist at that site for a sufficient period of time as set forth in the specification and in the present claims. However, applicant method claims do not recite the use hyaluronic acid that is a gel or gel-like composition; Neither does the language in the claims that pertains to the composition "having viscosity sufficient to persist at said site", equate to a gel-like hyaluronic acid composition or

excludes a solution. Furthermore, it cannot be concluded that a solution would not persist at a site of desired bone growth.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

4/2/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

April 1, 2007.